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10/519,536	12/28/2004	Yoshikatsu Kodama	2004_2037A	2533

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,536	KODAMA ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on June 18, 2007 is acknowledged. Claims 2-7 are pending and under consideration. Claims 2-4, 6, and 7 have been amended. Claims 2-7 are under examination.

Declaration

1. The revised 132 declaration by Yoshikatsu Kodama filed June 8, 2007 has been considered.

Objections Withdrawn

2. In view of Applicants' amendment to claims 2, 3, 6 and 7 the objection to the claims for reciting the genus and species of an organism (i.e. *Eimeria acervulina*) and not italicizing at each appearance and for misspelling "merozite" is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 2-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is being maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) Claims 2 and 6 have been amended to further specify the antigen used to immunize. Specifically, the amended claims recite "soluble outer membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*".

2) Applicants' have attached a Declaration under 37 CFR 1.132 by Dr. Kodama that further demonstrates that the claimed composition is capable of inducing protective immunity against chicken coccidiosis.

Applicant's arguments have been considered, but have not been deemed persuasive.

The claims are drawn to an anti-chicken coccidiosis composition for oral administration, comprising an antibody obtained from an egg of a chicken immunized with a soluble outer membrane of 18 to 27 kD from the merozoite of *Eimeria acervulina*, wherein the soluble membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*.

With regard to Points 1 and 2, while Applicant has amended the claims to recite "soluble outer membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*" and has submitted a revised Declaration by Dr. Kodama,

the instant claims are drawn to **a** soluble outer membrane protein wherein the soluble protein is F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*. Moreover, the claims recite that the outer membrane protein is 18 to 27 kD. The term "a" coupled with the range of 18 to 27 kD implies that there is more than one protein to choose from and that the F3 protein is not the only protein being described. For these reasons the rejection is maintained.

As previously presented, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claimed invention is directed to an anti-chicken coccidiosis composition for oral administration comprising an antibody obtained from an egg of a chicken immunized with a soluble outer membrane protein of 18 to 27 kD from the merozoite of *Eimeria acervulina*, wherein the soluble membrane protein is the soluble protein F3, which has a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima* which are associated with chicken coccidiosis, and a lactic acid bacterium. Subsequent claims are drawn to a method for preventing or treating chicken coccidiosis, which comprises orally administering to a bird an antibody obtained from an egg of a chicken immunized with a soluble outer membrane protein of 18 to 27 kD from the merozoite of *Eimeria acervulina,* wherein the soluble membrane protein is the soluble protein F3, which has a

common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina* which are associated with chicken coccidiosis.

Breadth of the claims: The claims encompass any antibody obtained from an egg of a chicken immunized with a any soluble outer membrane protein of 18 to 27 kD from the merozoite, wherein the soluble membrane protein is the soluble protein F3, which has a common immunogenicity shared among other strains of Eimeria which are associated with coccidiosis.

Direction or guidance presented in the specification: The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. The specification does not specifically teach which antibody is obtained from an egg of a chicken immunized with a soluble outer membrane protein of 18 to 27 kD from the merozoite wherein the soluble membrane protein is the soluble protein F3, which has a common immunogenicity shared among other strains of Eimeria which are associated with coccidiosis. It is unclear from the instant specification how one of skill in the art would know which antibody to obtain to meet the recitation of treating or preventing chicken coccidiosis. Moreover, the Declaration by Yoshikatsu Kodama filed on June 8, 2007 is not persuasive as the data presented therein is not commensurate in scope with the instant invention. The Declaration does not provide support for any antibody raised against any soluble outer membrane protein of 18 to 27 kD from the merozoite wherein the soluble membrane protein is the soluble protein F3, which has a common immunogenicity shared among other strains of Eimeria which are associated with coccidiosis as claimed. At best one

can conclude that when administering the composition of Example 1 (oocyst of *Eimeria acervulina* NA strain PE0101, *Eimeria tenella* NM strain PE0102, and *Eimeria maxima* NT strain PE0103) that you would yield a change in weight gain, food intake and overall survival rate, however one cannot conclude from the data presented that the chick is protected against coccidiosis due to a change in average weight, rate of maturity and productivity.

Presence or absence of working examples: There are no working examples provided to rectify the missing information in the instant specification pertaining to the claimed variant.

State of the prior art: Wallach et al. (Infection and Immunity, 1990; 58(2): 557-62) disclose that the antigenic diversity of *E. maxima* is considered to be a major problem in the development of a vaccine against this species. This is based on the finding that an infection with one strain of *E. maxima* does not protect against challenge with a different strain (page 561, 2nd column).

Moreover, Dalloul et al. (Expert Rev. Vaccines, 2006; 5(1): 143-163) disclose that increasing evidence shows the magnitude of complexity involved in host immune responses to Eimeria. Additional basic research is needed to ascertain the detailed immunologic and physiologic processes mediating protective immunity (see page 156). Lastly Dalloul et al. disclose that critical resources are severely lacking, which make is difficult to fulfill timely progress (page 156, concluding remarks).

Moreover, defining epitopes is not an easy task, as evidenced by Greenspan et al. (Nature Biotechnology 17: 936-937, 1999). Greenspan et al. recommends defining

an epitope by the structural characterization of the molecular interface between the antigen and the antibody necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of epitopes to which the members of the claimed genus of antibodies must bind, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antibodies. Moreover, since the specification has not identified which amino acids of the genus of epitopes to which the members of the claimed genus of antibodies must bind, which are critical or essential to the binding, one skilled in the art would not recognize that Applicant had possession of the claimed invention at the time the application was filed.

As evidenced by Bowie et al. (Science, 1990, 257:1306-1310), the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie

et al. teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of a soluble outer membrane protein is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue as the claims encompass a vast genus of antibodies specific for coccidiosis that are cross reactive with *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be

forced into undue experimentation to practice the claimed invention. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

4. The rejection claims 2-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) Claims 2 and 6 have been amended to further specify the antigen used to immunize. Specifically, the amended claims recite "soluble outer membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*".

Applicant's arguments have been considered, but have not been deemed persuasive.

The claims are drawn to an anti-chicken coccidiosis composition for oral

administration, comprising an antibody obtained from an egg of a chicken immunized with a soluble outer membrane of 18 to 27 kD from the merozoite of *Eimeria acervulina*, wherein the soluble membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*.

With regard to Point 1, while Applicant has amended the claims to recite "soluble outer membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*", the instant claims are drawn to **a** soluble outer membrane protein wherein the soluble protein is F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*. Moreover, the claims recite that the outer membrane protein is 18 to 27 kD. The term "a" coupled with the range of 18 to 27 kD implies that there is more than one protein to choose from and that the F3 protein is not the only protein being described.

Moreover, Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Although Applicant has amended the claims, they are not drawn to a specific antibody (i.e. defined) with the claimed specificity. Moreover, the specification does not fully characterize the antigen used to immunize (i.e. a soluble outer membrane protein of 18 to 27 kD from the merozoite of *Eimeria acervulina* outer membrane protein).

The courts have recently decided in Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin (CAFC, 02-1187, 1/20/2004) that a patentee of a

biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See Enzo Biochem II, 323 F.3d at 965; Regents, 119 F.3d at 1568. Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen. Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody

found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

Moreover, defining epitopes is not an easy task, as evidenced by Greenspan et al. (Nature Biotechnology 17: 936-937, 1999). Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows the epitope to which any given antibody binds can only be identified empirically. Even using a competition assay, the skilled artisan cannot determine whether an antibody binds the same epitope as another antibody because an antibody that competes with another does not necessarily bind the same epitope as the other; rather, one antibody may bind a spatially overlapping epitope to sterically hinder binding of the other. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of epitopes to which the members of the claimed genus of antibodies must bind, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antibodies. Moreover, since the specification has not identified which amino acids of the genus of epitopes to which the members of the claimed genus of antibodies must bind, which are critical or essential to the binding, one skilled in the art would not

recognize that Applicant had possession of the claimed invention at the time the application was filed.

As previously presented, claims 2-7 are drawn to a vast genus of antigenic outer membrane proteins and immunogenic fragments thereof. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

Moreover, the skilled artisan cannot envision the detailed structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must

describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of the claimed antigenic outer membrane protein or an immunogenic fragment thereof, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

However, the specification has not provided an adequate showing of which antibodies bind to antigens based solely on their common immunogenicity from among different species. The specification does not provide a written description of the invention of claims 2-7. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she

was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of antigenic outer membrane protein or an immunogenic fragment thereof, the skilled artisan could not immediately recognize or distinguish members of the claimed genus having preventive and/or reduced cellular and humoral immunogenicity. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of antigenic outer membrane protein or an immunogenic fragment thereof, is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillehoj et al. (Avian Diseases, 2000; 44; 379-389) further in view of Wells et al. (Antonie van Leeuwenhock, 1996; 70: 317-339).

The instant claims are drawn to an anti-chicken coccidiosis composition for oral

administration, comprising an antibody obtained from an egg of a chicken immunized with a soluble outer membrane of 18 to 27 kD from the merozoite of *Eimeria acervulina*, wherein the soluble membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima*.

Lillehoj et al. disclose an anti-chicken coccidiosis composition for oral administration to prevent chicken coccidiosis, comprising an antibody obtained from an egg of a chicken immunized with a soluble outer membrane of 18 to 27 kD from the merozoite of *Eimeria acervulina*, wherein the soluble membrane protein is the soluble protein F3 (see abstract). Lillehoj et al. disclose that chickens were immunized orally with said protein (see page 385). Moreover, Lillehoj et al. disclose that recombinant antigens expressed by different vector systems conferred different levels of immunity (see page 388).

Lillehoj et al. does not specifically disclose a lactic acid bacterium.

Wells et al. disclose the use of lactic acid bacteria as vaccine delivery vehicles. Moreover, Wells et al. disclose that the efficacy of bacterial vectors as vaccines is believed to depend on their invasiveness, capacity to survive and multiple, and on the occurrence of adequate levels of antigen gene expressions *in vivo* (see page 318).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Lillehoj et al. by combining a lactic acid bacteria to the claimed composition to simplify vaccine distribution and vaccine administration as well as provide a safe, effective vaccine that is capable of eliciting active immunity (see

page 317-introduction). One would have had a reasonable expectation, barring evidence to the contrary, that the composition and method would be effective for the prevention or treatment of chicken coccidiosis.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
8/28/07

ROBERT A. ZEMAN
PRIMARY EXAMINER